DEC 1 9 2000

K002815

21.0 510(K) SUMMARY

Submitter: **Jeneric/Pentron, Inc.**
Address: **53 North Plains Industrial Road**
Wallingford, Connecticut 06492
Contact Tel: 203-265-7397 X619
Contact Fax: 203-265-7662
Contact Person: Annmarie Tenero

Date Summary Prepared: September 7, 2000

Gold Core HF Pre Solder is a Dental Gold Alloy that is to be used for joining or repairing copings during the construction of crowns, bridges or substrate restorations prior to porcelain application. Gold Core HF Pre Solder is to be used in the dental laboratory.

We believe Gold Core HF Pre Solder is substantially equivalent to Bio 97, K991901, Jeneric/Pentron, Inc., Dental Gold alloy used in the construction of ceramic single unit crowns fixed restorations. Gold Core HF Pre Solder and Bio 97, K991901, both are almost pure gold with slight variations of other materials. These various materials do not affect the safety or effectiveness because the various materials are contained in other products currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2000

Ms. Annmarie Tenero
Jeneic/Pentron, Incorporated
53 North Plains Industrial Road
P.O. Box 724
Wallingford, Connecticut 06492-0724

Re: K002815
Trade Name: Gold Core Pre Solder
Regulatory Class: II
Product Code: EJT
Dated: December 7, 2000
Received: December 8, 2000

Dear Ms. Tenero:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Patricia Cucente/for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002815

5.0 INDICATION FOR USE STATEMENT

510(k) NUMBER (IF KNOWN): _____

DEVICE NAME: **GOLD CORE HF PRE SOLDER**

INDICATION FOR USE: Gold Core HF Pre Solder is a Dental Gold Alloy that is to be used for joining or repairing gold copings during the construction of crowns, bridges or substrate restorations prior to porcelain applications.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002815

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR** **Over –The-Counter-Use** _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**